
UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF TEXAS

JIMMY WAYNE MCGUIRE,

Plaintiff,

versus

ABBOTT LABORATORIES, INC.,

Defendant.

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CIVIL ACTION NO. 1:22-CV-197

MEMORANDUM AND ORDER

Pending before the court is Defendant Abbott Laboratories, Inc.’s (“Abbott”) Second Motion to Dismiss (#27), wherein it seeks dismissal of all of Plaintiff Jimmy Wayne McGuire’s (“McGuire”) claims. Having considered the motion, the record, and the applicable law, the court is of the opinion that Abbott’s motion should be granted.

I. Background

McGuire alleges that an implantable cardioverter-defibrillator (“ICD”) was placed in his chest on October 13, 2017, in order to treat certain cardiac health issues he was experiencing. The ICD was a Fortify Assura DR (“Fortify Assura”), Model No. CD2357-40Q, which was manufactured, marketed, and sold by Abbott. McGuire claims that he suffered shocks from the Fortify Assura when it malfunctioned on April 14, 2020. McGuire contends that he was taken to Christus St. Elizabeth Hospital in Beaumont, Texas, for treatment the same day, and that he was subsequently transported to Houston Methodist Hospital where the Fortify Assura was replaced with a different ICD manufactured by Abbott. McGuire asserts that he sustained mental and physical injuries as a result of the malfunction.

McGuire filed a lawsuit against Abbott in the 88th Judicial District Court of Hardin County, Texas, asserting product liability claims due to alleged manufacturing, design, and marketing defects of the device, as well as negligence claims, related to the Fortify Assura. Abbott removed the case to the United States District Court for the Eastern District of Texas, Beaumont Division. On September 15, 2022, the court conditionally granted Abbott's First Motion to Dismiss (#10), but allowed McGuire an opportunity to amend his pleadings (#23). On October 17, 2022, McGuire filed an Amended Complaint (#24), which alleges the following "five theories of recovery": (1) failure to warn; (2) manufacturing defect; (3) negligence in the marketing and manufacturing of the device; (4) negligent misrepresentation; and (5) breach of express warranty. On November 11, 2022, Abbott filed the pending motion to dismiss on the basis that McGuire failed to plead any legally sufficient claims and that all of his claims are preempted by federal law. McGuire did not file a response.

II. Analysis

A. Rule 12(b)(6) Standard

A motion to dismiss for failure to state a claim upon which relief can be granted under Rule 12(b)(6) of the Federal Rules of Civil Procedure tests only the formal sufficiency of the statement of a claim for relief and is "appropriate when a defendant attacks the complaint because it fails to state a legally cognizable claim." *Ramming v. United States*, 281 F.3d 158, 161 (5th Cir. 2001), *cert. denied*, 536 U.S. 960 (2002); *accord Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (holding that in order "[t]o survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face"); *Spano ex rel. C.S. v. Whole Foods, Inc.*, 65 F.4th 260, 2023 WL 2943005, at *2 (5th Cir. Apr. 14, 2023) (quoting

Innova Hosp. San Antonio, Ltd. P'ship v. Blue Cross & Blue Shield of Ga., Inc., 892 F.3d 719, 726 (5th Cir. 2018)); *IberiaBank Corp. v. Ill. Union Ins. Co.*, 953 F.3d 339, 345 (5th Cir. 2020); *Walker v. Beaumont Indep. Sch. Dist.*, 938 F.3d 724, 734 (5th Cir. 2019). Such a motion is “not meant to resolve disputed facts or test the merits of a lawsuit” and “instead must show that, even in the plaintiff’s best-case scenario, the complaint does not state a plausible case for relief.” *Sewell v. Monroe City Sch. Bd.*, 974 F.3d 577, 581 (5th Cir. 2020); *Oyekwe v. Rsch. Now Grp., Inc.*, 542 F. Supp. 3d 496, 502 (N.D. Tex. 2021); 5B CHARLES ALAN WRIGHT & ARTHUR R. MILLER, FEDERAL PRACTICE AND PROCEDURE § 1356 (3d ed. 2019). In ruling on such a motion, the court must accept the factual allegations of the complaint as true, view them in a light most favorable to the plaintiff, and draw all reasonable inferences in favor of the plaintiff. *Hernandez v. Mesa*, 582 U.S. 548, 550 (2017); *Ramirez v. Guadarrama*, 3 F.4th 129, 133 (5th Cir. 2021), *cert. denied*, 142 S. Ct. 2571 (2022); *IberiaBank Corp.*, 953 F.3d at 345 (citing *Leal v. McHugh*, 731 F.3d 405, 410 (5th Cir. 2013)); *Walker*, 938 F.3d at 735. The court, however, does not “strain to find inferences favorable to the plaintiff[]” or “accept conclusory allegations, unwarranted deductions, or legal conclusions.” *Southland Sec. Corp. INSpire Ins. Sols., Inc.*, 365 F.3d 353, 361 (5th Cir. 2004); *accord Ruvalcaba v. Angleton Indep. Sch. Dist.*, No. 20-40491, 2022 WL 340592, at *3 (5th Cir. Feb. 4, 2022); *Modelist v. Miller*, 445 F. App’x 737, 739 (5th Cir. 2011); *Jones v. Dickerson*, No. CV H-19-3876, 2020 WL 6504456, at *2 (S.D. Tex. Nov. 5, 2020).

“[T]he plaintiff’s complaint [must] be stated with enough clarity to enable a court or an opposing party to determine whether a claim is sufficiently alleged.” *Oscar Renda Contracting, Inc. v. Lubbock*, 463 F.3d 378, 381 (5th Cir. 2006) (citing *Elliott v. Foufas*, 867 F.2d 877, 880

(5th Cir. 1989)), *cert. denied*, 549 U.S. 1339 (2007); *Ramming*, 281 F.3d at 161. The “[f]actual allegations must be enough to raise a right to relief above the speculative level.” *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007); *accord Spano ex rel. C.S.*, 2023 WL 2943005, at *2; *King v. Baylor Univ.*, 46 F.4th 344, 355 (5th Cir. 2022); *Davis v. Tex. Health & Hum. Servs. Comm’n*, 761 F. App’x 451, 454 (5th Cir. 2019); *Lee v. Verizon Commc’ns, Inc.*, 837 F.3d 523, 533 (5th Cir. 2016), *cert. denied*, 137 S. Ct. 1374 (2017). “Where the well-pleaded facts of a complaint do not permit a court to infer more than the mere possibility of misconduct, the complaint has alleged—but it has not ‘show[n]’—‘that the pleader is entitled to relief.’” *Walker*, 938 F.3d at 734 (quoting *Iqbal*, 556 U.S. at 678); *accord King*, 46 F.4th at 355. Hence, “a complaint’s allegations ‘must make relief plausible, not merely conceivable, when taken as true.’” *Walker*, 938 F.3d at 734 (quoting *United States ex rel. Grubbs v. Kanneganti*, 565 F.3d 180, 186 (5th Cir. 2009)); *see King*, 46 F.4th at 355; *Longoria ex rel. M.L. v. San Benito Indep. Consol. Sch. Dist.*, 942 F.3d 258, 263 (5th Cir. 2019) (“Though the complaint need not contain ‘detailed factual allegations,’ it must contain sufficient factual material to ‘allow[] the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.’” (quoting *Iqbal*, 556 U.S. at 678)).

Generally, the court may not look beyond the four corners of the plaintiff’s pleadings. *Indest v. Freeman Decorating, Inc.*, 164 F.3d 258, 261 (5th Cir. 1999); *see King*, 46 F.4th at 356; *Wilson v. Birnberg*, 667 F.3d 591, 595 (5th Cir.), *cert. denied*, 567 U.S. 936 (2012); *Hicks v. Lingle*, 370 F. App’x 497, 497 (5th Cir.), *cert. denied*, 562 U.S. 1111 (2010). The court may, however, consider “documents attached to the complaint, and any documents attached to the motion to dismiss that are central to the claim and referenced by the complaint.” *Lone Star Fund*

V (U.S.), L.P. v. Barclays Bank PLC, 594 F.3d 383, 387 (5th Cir. 2010); *see Innova Hosp. San Antonio, L.P.*, 892 F.3d at 726 (“[A] court ruling on a 12(b)(6) motion may rely on the complaint, its proper attachments, ‘documents incorporated into the complaint by reference, and matters of which a court may take judicial notice.’” (quoting *Wolcott v. Sebelius*, 635 F.3d 757, 763 (5th Cir. 2011))); *Gines v. D.R. Horton, Inc.*, 699 F.3d 812, 820 (5th Cir. 2012); *Funk v. Stryker Corp.*, 631 F.3d 777, 783 (5th Cir. 2011).

“The question therefore is whether in the light most favorable to the plaintiff and with every doubt resolved in his behalf, the complaint states any valid claim for relief.” *Collins v. Morgan Stanley Dean Witter*, 224 F.3d 496, 498 (5th Cir. 2000); *accord Thompson v. City of Waco*, 764 F.3d 500, 503 (5th Cir. 2014) (noting that at the 12(b)(6) stage the court’s task “is to determine whether the plaintiff [has] stated a legally cognizable claim that is plausible, not evaluate the plaintiff’s likelihood of success”); *Leal*, 731 F.3d at 410. “In other words, a motion to dismiss an action for failure to state a claim ‘admits the facts alleged in the complaint, but challenges plaintiff’s rights to relief based upon those facts.’” *Ramming*, 281 F.3d at 161-62 (quoting *Tel-Phonic Servs., Inc. v. TBS Int’l, Inc.*, 975 F.2d 1134, 1137 (5th Cir. 1992)); *accord Yazdi v. Lafayette Par. Sch. Bd.*, No. 6:18-CV-00510, 2020 WL 5876703, at *2 (W.D. La. Sept. 30, 2020); *Lopez-Flores v. Ibarra*, No. 1:17-CV-00105, 2018 WL 6577955, at *2 (S.D. Tex. Mar. 12, 2018).

A Rule 12(b)(6) motion to dismiss must be read in conjunction with Rule 8(a) of the Federal Rules of Civil Procedure. *Twombly*, 550 U.S. at 555. Accordingly, a district court should not dismiss a complaint for failure to state a claim unless a plaintiff has failed to plead “enough facts to state a claim to relief that is plausible on its face.” *Id.* at 570; *accord King*,

46 F.4th at 355; *IberiaBank Corp.*, 953 F.3d at 345 (quoting *Iqbal*, 556 U.S. at 678); *Zastrow v. Hous. Auto Imps. Greenway Ltd.*, 789 F.3d 553, 559 (5th Cir. 2015); *Leal*, 731 F.3d at 410; *Wilson*, 667 F.3d at 595. “A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” *Coleman v. Sweetin*, 745 F.3d 756, 763 (5th Cir. 2014) (quoting *Iqbal*, 556 U.S. at 678); *accord King*, 46 F.4th at 355-56; *Thompson*, 764 F.3d at 503; *Harold H. Huggins Realty, Inc. v. FNC, Inc.*, 634 F.3d 787, 796 (5th Cir. 2011).

“The plausibility standard is not akin to a ‘probability requirement,’ but it asks for more than a sheer possibility that a defendant has acted unlawfully.” *Walker*, 938 F.3d at 734 (quoting *Iqbal*, 556 U.S. at 678); *accord King*, 46 F.4th at 356. “Factual allegations that are ‘merely consistent with a defendant’s liability, stop short of the line between possibility and plausibility of entitlement to relief,’ and thus are inadequate.” *Walker*, 938 F.3d at 734. “Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice.” *Shaw v. Villanueva*, 918 F.3d 414, 415 (5th Cir. 2019) (quoting *Iqbal*, 556 U.S. at 678); *accord King*, 46 F.4th at 356 (“[C]ourts ‘do not accept as true conclusory allegations, unwarranted factual inferences, or legal conclusions.’” (quoting *Plotkin v. IP Axxess Inc.*, 407 F.3d 690, 696 (5th Cir. 2005))); *Gibson v. Tex. Dep’t of Ins.–Div. of Workers’ Comp.*, 700 F.3d 227, 233 (5th Cir. 2012). “Nor does a complaint suffice if it tenders ‘naked assertion[s]’ devoid of ‘further factual enhancement.’” *Iqbal*, 556 U.S. at 678 (quoting *Twombly*, 550 U.S. at 557); *Shaw*, 918 F.3d at 419.

“While legal conclusions can provide the framework of a complaint, they must be supported by factual allegations.” *Iqbal*, 556 U.S. at 679; *Shaw*, 918 F.3d at 419; *Collins v.*

Robinson Indep. Sch. Dist., No. W-21-CV-00657, 2022 WL 2019294, at *1 (W.D. Tex. June 6, 2022). In other words, to state a cognizable cause of action, the complaint must allege sufficient facts to “nudge” the claims “across the line from conceivable to plausible.” *Twombly*, 550 U.S. at 570; *Leal*, 731 F.3d at 410; *see Walker*, 938 F.3d at 734 (quoting *Grubbs*, 565 F.3d at 186).

B. Federal Preemption

As discussed in the court’s prior order, § 360k(a) of the Medical Device Amendments of 1976 (“MDA”) prohibits states from establishing safety or effectiveness standards that are different from, or in addition to, the requirements of the Federal Food, Drug, and Cosmetic Act. 21 U.S.C. § 360k(a). Section 360(k) preemption applies to Class III devices approved through the Food and Drug Administration’s (“FDA”) pre-market approval (“PMA”) process. *Bass v. Stryker Corp.*, 669 F.3d 501, 507 (5th Cir. 2012); *Rodriguez v. Am. Med. Sys., Inc.*, 597 F. App’x 226, 228 (5th Cir. 2014); *see Riegel v. Medtronic, Inc.*, 552 U.S. 312, 321-30 (2008). The parties agree that the Fortify Assura is a Class III, FDA-approved medical device that has undergone the PMA process.

In order to avoid preemption, therefore, McGuire’s tort claims must be considered “parallel claims.” *See Riegel*, 552 U.S. at 330; *Reddick v. Medtronic, Inc.*, No. 21-30169, 2022 WL 715494, at *2 (5th Cir. Mar. 9, 2022); *Naquin v. Medtronic, Inc.*, No. 20-30793, 2021 WL 4848838, *3 (5th Cir. 2021); *Rodriguez*, 597 F. App’x at 229. “A state law claim is ‘parallel’ if it ‘provid[es] a damages remedy . . . premised on a violation of FDA regulations.’” *Reddick*, 2022 WL 715494, at *2 (quoting *Riegel*, 552 U.S. at 330); *Rodriguez*, 597 F. App’x at 228; *Bass*, 669 F.3d at 510-12 (5th Cir. 2012). “[T]he state duties in such a case ‘parallel,’ rather than add to, federal requirements.” *Rodriguez*, 597 F. App’x at 228 (quoting *Riegel*, 552 U.S. at 330).

“Even if a state law claim is parallel, a district court may still dismiss it if the claim is ‘impermissibly conclusory and vague.’” *Reddick*, 2022 WL 715494, at *2 (“[A] complaint that does not ‘specify the manufacturing defect,’ ‘specify a causal connection between the failure of the specific manufacturing process and the specific defect in the process that caused the personal injury,’ or ‘tell us how the manufacturing process failed, or how it deviated from the FDA approved manufacturing process’ is insufficient to state a parallel products liability claim.”); *Rodriguez*, 597 F. App’x at 230 (holding that the plaintiff failed to state a parallel manufacturing or design defect claim when his complaint did not plead a violation of any federal requirement relating to design or manufacturing of the implant and he did not allege a specific defect in the manufacturing process or design, any deviation from the FDA-approved design or manufacturing processes, or any causal connection between a violation of federal requirements and his injuries); *Funk*, 631 F.3d at 782 (holding that the plaintiff’s pleadings were too conclusory to state a parallel claim when the complaint did not specify the manufacturing defect, a causal connection between a failure of the manufacturing process or a specific defect in the process that caused the personal injury, or how the process deviated from the FDA-approved manufacturing process).

C. McGuire’s Claims

The Amended Complaint includes causes of action for failure to warn and negligent marketing defect, strict liability and negligent manufacturing defect, negligent misrepresentation, and breach of express warranty. Abbott asserts that McGuire has failed to state a claim, and in any event, these claims are preempted by the MDA.

1. Failure to Warn and Negligent Marketing

McGuire appears to base his failure to warn and negligent marketing defect claims on Abbott’s failure to report adverse incidents to the FDA. McGuire’s Amended Complaint states that Abbott was “required by the FDA to report adverse incidents” involving the Fortify Assura, yet “it failed to report adverse incidents.”¹

Products liability claims in Texas fall into three categories: design defect, manufacturing defect, and marketing defect, also referred to as warning defect. *Am. Tobacco Co. v. Grinnell*, 951 S.W.2d 420, 426 & n.1 (Tex. 1997); *accord Smith v. FCA US LLC*, No. 3:22-CV-73-L, 2023 WL 361095, at *3 (N.D. Tex. Jan. 23, 2023); *see Meritor Auto., Inc. v. Ruan Leasing Co.*, 44 S.W.3d 86, 88 (Tex. 2001); *Caterpillar, Inc. v. Shears*, 911 S.W.2d 379, 382 (Tex. 1995); *Tech. Chem. Co. v. Jacobs*, 480 S.W.2d 602, 604-05 (Tex. 1972); *Borg-Warner Corp. v. Flores*, 153 S.W.3d 209, 220 (Tex. App.—Corpus Christi 2004, no pet.).

“The Texas Supreme Court has explained that ‘a defendant’s failure to warn of a product’s potential dangers when warnings are required is a type of marketing defect. . . . Generally, a manufacturer has a duty to warn if it knows or should know of the potential harm to a user because of the nature of its product.’” *Smith v. Robin Am., Inc.*, 484 F. App’x 908, 912 (5th Cir. 2012) (quoting *Grinnell*, 951 S.W.2d at 426); *accord Smith*, 2023 WL 361095, at *3; *see Shears*, 911 S.W.2d at 382; *Lucas v. Tex. Indus., Inc.*, 696 S.W.2d 372, 377 (Tex. 1985). Under Texas law, “[t]o prevail on their marketing-defect claims, plaintiffs [must] show (a) the warning was defective and (b) the defect was a producing cause of the injury.” *In re DePuy Orthopaedics, Inc., Pinnacle*

¹ Under federal law, device manufacturers must report any incident to the FDA where their device “may have caused or contributed to a death or serious injury.” 21 C.F.R. § 803.50(a).

Hip Implant Prod. Liab. Litig., 888 F.3d 753, 772 (5th Cir. 2018) (citing *Ackermann v. Wyeth Pharm.*, 526 F.3d 203, 208 (5th Cir. 2008)); accord *Hale v. Metrex Rsh. Corp.*, 963 F.3d 424, 428 (5th Cir. 2020). Texas applies the learned intermediary doctrine in medical products liability actions. *In re DePuy Orthopaedics, Inc., Pinnacle Hip Implant Prod. Liab. Litig.*, 888 F.3d at 774. Under the learned intermediary doctrine, “the manufacturer . . . satisfies its duty to warn the end user of its product’s potential risks by providing an adequate warning to a ‘learned intermediary,’ who then assumes the duty to pass on the necessary warnings to the end user.” *Id.* (quoting *Centocor, Inc. v. Hamilton*, 372 S.W.3d 140, 142 (Tex. 2012)).

As Abbott observes, McGuire’s Amended Complaint fails to do more than assert conclusory allegations regarding his failure to warn and marketing defect claims. While McGuire states that Abbott “failed to report adverse incidents,” he does not specify what warning was defective, what adverse incident(s) was(were) not reported, or how such warning or report would have prevented the alleged harm. *See McKenzie v. Abbott Lab’ys*, 563 F. Supp. 3d 512, 524 (M.D. La. 2021) (holding that the pleadings failed to allege a causal link between the defendant’s alleged failure to report adverse incidents and the patient’s injuries when there were not sufficient facts from which the court could infer that it was plausible that the reports of those events would have reached the patient’s doctor in time for him to act differently when implanting the medical device); *De La Paz v. Bayer Healthcare LLC*, 159 F. Supp. 3d 1085, 1093 (N.D. Cal. 2016) (stating that “numerous district court decisions have . . . recognized that a causal link between a manufacturer’s failure to warn the FDA and a plaintiff’s injury is a necessary element” of a claim premised on failure to report adverse events to the FDA). Accordingly, McGuire’s claims for

failure to warn and negligent marketing are dismissed for failure to state a claim under Rule 12(b)(6).

2. Manufacturing Defect

McGuire’s pleading attempts to cast his strict liability and negligent manufacturing defect claims as parallel claims to avoid preemption. McGuire asserts that “[a]ny deviation from the FDA’s approved design for the [Fortify Assura] would violate federal regulations,” and thus, to the extent that his claims rely on such deviations, they “would not differ from or add to preexisting federal obligations.”

Under Texas law, “[a] manufacturing defect exists when a product deviates, in its construction or quality, from the specifications or planned output in a manner that renders it unreasonably dangerous.” *Norman v. Bodum USA, Inc.*, 44 F.4th 270, 272 (5th Cir. 2022) (quoting *Ford Motor Co. v. Ridgway*, 135 S.W.3d 598, 600 (Tex. 2004)); *Casey v. Toyota Motor Eng’g & Mfg. N. Am., Inc.*, 770 F.3d 322, 326 (5th Cir. 2014); *Briggs v. Endologix, Inc.*, No. 3:22-CV-00290, 2023 WL 2716592, at *3 (S.D. Tex. Mar. 30, 2023); *Gharda USA, Inc. v. Control Sols., Inc.*, 464 S.W.3d 338, 352 (Tex. 2015); *BIC Pen Corp. v. Carter*, 346 S.W.3d 533, 540 (Tex. 2011); *Ford Motor Co. v. Ledesma*, 242 S.W.3d 32, 46 n.16 (Tex. 2007) (quoting *Grinnell*, 951 S.W.2d at 434). In a manufacturing defect case, “[a] plaintiff ‘must prove that the product was defective when it left the hands of the manufacturer and that the defect was a producing cause of the plaintiff’s injuries.’” *Norman*, 44 F.4th at 272 (quoting *Ridgway*, 135 S.W.3d at 600). To prove a manufacturing defect, “a specific defect must be identified by competent evidence and other possible causes must be ruled out.” *Ledesma*, 242 S.W.3d at 42 (quoting *Nissan Motor Co. v. Armstrong*, 145 S.W.3d 131, 137 (Tex. 2004)); *see Casey*, 770 F.3d

at 326; *Ridgway*, 135 S.W.3d at 601. The “touchstone” of such a claim “is proof that the allegedly defective product differs from other products in the same product line.” *Harrison v. Medtronic, Inc.*, No. 22-10201, 2022 WL 17443711, at *2 (5th Cir. Dec. 6, 2022) (quoting *Casey*, 770 F.3d at 329).

“Texas law does not generally recognize a product failure or malfunction, standing alone, as sufficient proof of a product defect.” *Casey*, 770 F.3d at 326; *accord Norman*, 44 F.4th at 272. Nevertheless, “[i]f the plaintiff ‘has no evidence of a specific defect in the design or manufacture of the product, he may offer evidence of its malfunction as circumstantial proof of the product’s defect.’” *Shaun T. Mian Corp. v. Hewlett-Packard Co.*, 237 S.W.3d 851, 858 (Tex. App.—Dallas 2007, pet. denied) (quoting *Gen. Motors Corp. v. Hopkins*, 548 S.W.2d 344, 349-50 (Tex. 1977), *overruled in part on other grounds by Turner v. Gen. Motors Corp.*, 584 S.W.2d 844, 851 (Tex. 1979)); *see Norman*, 44 F.4th at 272. To plead a manufacturing defect claim adequately, a plaintiff must allege more than the mere fact of a product-related accident. *Elmazouni v. Mylan, Inc.*, 220 F. Supp. 3d 736, 741 (N.D. Tex. 2016) (holding that Plaintiffs’ claiming a manufacturing defect because “it [the product] malfunctioned” and “did not perform as intended or designed” was insufficient under Rule 12(b)(6) standards); *see Cofresi v. Medtronic, Inc.*, No. 5:19-CV-1222-DAE, 2020 WL 1887862, at *4 (W.D. Tex. Mar. 30, 2020) (holding that the plaintiff failed to plead a manufacturing defect when he contended that the entire design of the product was defective); *McAndrews v. C.R. Bard, Inc.*, No. H-14-2504, 2015 WL 2089432, at *2 (S.D. Tex. May 5, 2015) (“Plaintiff’s complaint does not allege any defect from specifications or planned output.”); *Eckhardt v. Qualitest Pharm. Inc.*, 858 F. Supp. 2d 792, 800 (S.D. Tex. 2012) (“The Court finds that the complaint contains no more than conclusory

allegations that there was a manufacturing defect.”). Rather, a plaintiff must allege a specific deviation from the product’s intended design that allegedly caused the injury. *Norman*, 44 F.4th at 272 (citing *Casey*, 770 F.3d at 326).

Here, McGuire’s Amended Complaint “is impermissibly conclusory and vague; it does not specify the manufacturing defect; nor does it specify a causal connection between the failure of the specific manufacturing process and the specific defect in the process that caused the personal injury. Nor does the [Amended Complaint] tell us how the manufacturing process failed, or how it deviated from the FDA approved manufacturing process.” *Funk*, 631 F.3d at 782; *accord Briggs*, 2023 WL 2716592, at *3; *Celino v. Biotronik, Inc.*, 536 F. Supp. 3d 89, 104 (E.D. La. 2021) (“The amended complaint is, to say the least, ‘light on factual allegations and heavy on conclusory statements;’ these allegations are far too conclusory to be of any help.” (quoting *Scianneaux v. St. Jude Med. S.C., Inc.*, 961 F. Supp. 2d 808, 813 (E.D. La. 2013))); *Yosowitz v. Covidien LP*, 182 F. Supp. 3d 683, 694 (S.D. Tex. 2016). Thus, the Amended Complaint fails to plead adequately McGuire’s strict liability and negligent manufacturing defect claims.

3. Negligent Misrepresentation

McGuire alleges that Abbott marketed the Fortify Assura “as being safer than other pacemakers, despite its knowledge that this model pacemaker was causing serious medical problems such as what McGuire suffered.” Under Texas law, to recover for negligent misrepresentation, the plaintiff must establish that:

- (1) a representation was made by a defendant in the course of his business, or in a transaction in which he has a pecuniary interest;
- (2) the defendant supplied “false information” for the guidance of others in their business;

(3) the defendant did not exercise reasonable care or competence in obtaining or communicating the information; and

(4) the plaintiff suffer[ed] pecuniary loss by justifiably relying on the representation.

Colbert v. Wells Fargo Bank, N.A., 850 F. App'x 870, 876 (5th Cir. 2021) (quoting *Fed. Land Bank Ass'n v. Sloane*, 825 S.W.2d 439, 442 (Tex. 1991)); *Life Partners Creditors' Tr. v. Cowley (In re Life Partners Holdings, Inc.)*, 926 F.3d 103, 123 (5th Cir. 2019); *JPMorgan Chase Bank, N.A. v. Orca Assets G.P., L.L.C.*, 546 S.W.3d 648, 653-54 (Tex. 2018).

McGuire contends that his negligent misrepresentation claim parallels federal requirements because “[w]hen a manufacturer makes claims about its device that [it] is safer than completing [sic] devices, it steps out of the ‘protected zone of FDA-approved warranties’ and into its ongoing obligation to disseminate truthful and non-misleading information.” McGuire, however, does not allege that Abbott’s alleged statement was false; specify when such representations were made; contend that he relied on these statements; or identify any causal connection between the purported misrepresentation and McGuire’s injuries. In view of these shortcomings, McGuire has failed to plead sufficiently a claim for negligent misrepresentation.

4. Breach of Express Warranty

McGuire similarly points to Abbott’s alleged statements regarding the comparative safety of the Fortify Assura as the basis for his breach of express warranty claim.

“An express warranty is created when a seller makes an affirmation of fact or a promise to the purchaser, that relates to the sale and warrants a conformity to the affirmation as promised.” *McNeely v. Salado Crossing Holding, L.P.*, No. 04-16-00678-CV, 2017 WL 2561551, at *3 (Tex. App.—San Antonio June 14, 2017, no pet.) (quoting *Head v. U.S. Inspect DFW, Inc.*, 159 S.W.3d 731, 746 (Tex. App.—Fort Worth 2005, no pet.)); see *Patton v. Meridian Sec. Ins. Co.*, 617 F.

Supp. 3d 516, 545 (N.D. Tex. 2022) (“[W]arranties describe attributes, suitability for a particular purpose, and ownership of what is sold.” (quoting *Lyda Constructors, Inc. v. Butler Mfg. Co.*, 103 S.W.3d 632, 637 (Tex. App.—San Antonio 2003, no pet.))). In Texas, to recover for a breach of an express warranty, the plaintiff must prove:

- (1) the defendant-seller made an express affirmation of fact or promise relating to the goods;
- (2) that affirmation of fact or promise became a part of the basis of the bargain;
- (3) the buyer, in making the purchase, relied on the affirmation of fact or promise;
- (4) the goods sold by the seller failed to comply with the affirmation of fact or promise made by the seller;
- (5) the plaintiff suffered damages; and
- (6) the failure of the product to comply was the proximate cause of the plaintiff’s damages.

See TEX. BUS. & COM. CODE § 2.313; *Patton*, 2022 WL 2992878, *23 (quoting *Lindemann v. Eli Lilly & Co.*, 816 F.2d 199, 202 (5th Cir. 1987)); *Alex v. T-Mobile USA, Inc.*, No. 3:17-CV-1532, 2018 WL 806992, at *6 (N.D. Tex. Feb. 9, 2018).

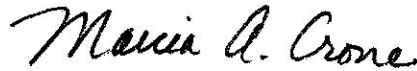
Here, as the court has already observed, McGuire has failed to allege that Abbott’s statement concerning the relative safety of the Fortify Assura was in fact false. McGuire simply states that “Abbott violated the FDA’s conditional approval by marketing the [Fortify Assura] as being safer than other pacemakers, despite its knowledge that this model pacemaker was causing serious medical problems such as what McGuire suffered.” McGuire does not contend that there were other ICDs that were safer than the Fortify Assura. Moreover, McGuire does not assert that he relied on Abbott’s purported statement concerning the relative safety of the Fortify Assura, nor

does he allege that this statement was the proximate cause of his injuries. Thus, McGuire has failed to plead adequately a cause of action for breach of warranty.

III. Conclusion

Accordingly, Abbott's Second Motion to Dismiss (#27) is GRANTED. McGuire's claims against Abbott are DISMISSED with prejudice.

SIGNED at Beaumont, Texas, this 3rd day of May, 2023.

A handwritten signature in black ink, reading "Marcia A. Crone". The signature is written in a cursive, flowing style. Below the signature is a horizontal line.

MARCIA A. CRONE
UNITED STATES DISTRICT JUDGE